



## SCOPE OF NORTH-WEST UNIVERSITY SCIENTIFIC- AND RESEARCH ETHICS COMMITTEES

### 1. BACKGROUND

Scientific integrity and research ethics forms an integral part of the quality of research in any discipline. These differential contexts of disciplines, different risk levels of studies (*no to high*), as well as institutional, national and international legal and regulatory requirements, require the development of different sets of expertise, experience, and capacity in scientific/proposal committees (SC) and research ethics committees (RECs), to effectively review and monitor such studies. It also considers responsible planning, conduct and reporting of research findings. Research also require different levels of scientific and ethical consideration and oversight by these SCs and RECs.

Ethics specifically not only considers moral issues, the protection of research participants (humans and animals), as well as the impact of research on the environment, but also protects researchers and the institution. The approach to research ethics may differ in various disciplines, but they all share a common set of minimum requirements. In multi-, inter-, and transdisciplinary research, a complimentary approach is required.

Therefore, the North-West University has positioned itself by establishing a specific scientific- and research ethics committee structure. This document provides a guideline to SCs and RECs to explain the scope of studies to be first reviewed by a SCs and then the appropriate REC within the NWU, as well as a roadmap for referral of studies to the appropriately positioned REC (Note: See the ethics clearance flow process in appendix A).

All of these RECs have been approved by the Faculty Boards of the various faculties within which they reside as well as the Senate Committee for Research Ethics (SCRE). Some of these RECs are also legally required to be registered with the National Health Research Ethics Council (NHREC) as a national regulatory body.

### 2 TERMINOLOGY:

#### 2.1 Ethics clearance

Ethics clearance refers to the process of review and decision-making by a REC about the final risk level of a study and whether it has to undergo an expedited or full face-to-face ethics review by the REC.

## **2.2 Ethics review**

Ethics review refers to the process of an independent expedited or full face-to-face review and decision-making, based on a SOP of the REC. The process is based on the scientific principles of a proposal's adherence to minimal ethical norms and standards in research activities, as well as giving attention to all possible ethical considerations. The REC can approve, require amendments or reject a proposal. Approval includes the final risk level of the study, the duration of the study (one year with further extension based on review of a monitoring report or application for extension) and reporting requirements. All amendments should be approved and adverse effects or incidents reported to the REC. A formal letter of decision by the REC is issued to the researcher/postgraduate student.

## **2.3 Risk**

Risk refers to the potential of harm occurring to a participant as a result of participation in research. Possibility and extent of harm e.g. mild or severe, should be assessed.

## **2.4 Vulnerability**

Vulnerability of the participant refers to the diminished ability to fully safeguard one's own interest in the context of a specific research project/study. This may be caused by limited capacity or limited access to social goods like rights, opportunities and power; limited freedom to make choices; or relatively incapable of protecting own interest. Vulnerability is not an absolute condition but rather occurs on a sliding scale depending on personal and environmental circumstances (DoH, 2015; Regulation relating to research with human participants. R.719 of 19 September 2014).

## **2.5 Context**

Context refers to the nature of the study e.g. health, non-health, animal etc.

## **2.6 Health research**

Health research is defined as *“research that contribute to biological, clinical, psychological or social welfare matters, including processes as regards humans; causes and effects of and responses to disease; effects of the environment; health care systems; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care”* (DoH, 2015:7 1.1.3).

## **2.7 Health-related research**

Health related research refers to any research conducted by disciplines other than health disciplines about topics or participants within the field of health or investigating or striving to improve the bio-psycho-social wellbeing of human participants.

## **3. SCIENTIFIC/PROPOSAL COMMITTEES (SC)**

### **3.1 Purpose of scientific/proposal committees**

In the *Terms of Reference for the Management of Research Ethics at the North-West University* document, approved by senate in November 2018 under point 1.2.5 it states that “*before any research may be conducted scientific approval must be granted for a project/study by the relevant scientific/proposal committee*”.

The scientific/proposal committee (SC) will review and approve the science of the project/study and make a preliminary assessment of the:

- *Scientific validity and integrity*
- *The potential risk level*
- *Whether there are potential vulnerable participants involved*
- *The context of the study*

The SC then refers the application to an appropriate REC for ethics clearance.

### **3.2 Issuing of a letter of scientific approval:**

In the case of a *low to high risk study* that is referred for review by a REC, the SC should issue a *letter of scientific approval* to the researcher signed by the chairperson indicating their decision. The letter is attached to the ethics application.

### **3.3 The referral process for ethics clearance:**

*All studies* are referred to an appropriate REC for ethics clearance.

The decision to which REC the SC should refer the study is based on 1) the risk level of the study (participants or researchers), 2) whether it involves vulnerable participants, 3) whether it will negatively impact on the environment, 4) the risk to the reputation of the NWU, as well as 5) the nature of the study.

- A *no risk study* is considered by the SC and recommended to the Faculty REC (FREC) for clearance using a *template* and *linking the proposal*.
- A *low risk study* is considered by the SC and recommended to the Faculty REC for clearance and review (*except in the case of health or health-related studies where it is referred to NWU-HREC; or animal studies where it is referred to either NWU-AnimCare-REC or NWU-AnimProd-REC*).
- A *medium to high risk study* or a *study involving vulnerable participants*, is considered by the SC and recommended to the appropriate NHREC-registered REC for ethics clearance and review.
- A *health or health-related study* is considered by the SC and recommended to the NWU-HREC for clearance and review *irrespective of the risk level*.
- An *animal research study* is considered by the SC and recommended to the appropriate animal REC for clearance and review *irrespective of the risk level* (NWU-AnimCare-REC or NWU-AnimProd-REC).
- A study with a *potential negative impact on the environment* is considered by the SC and recommended to the appropriate REC for clearance and review.
- A *study with potential reputational damage to the NWU* is considered by the SC and recommended to the appropriate REC for clearance and review.

#### 4. FACULTY RESEARCH ETHICS COMMITTEES (FREC)

Each of the eight Faculties of the North-West University have at least one Faculty Research Ethics Committee (FREC) responsible for reviewing *no risk to low risk studies* as well as overseeing and managing compliance with the requirements of ethical research in *no and low risk studies*.

Note: The exception is *health and health-related studies*; and *animal studies* where *low risk* is also referred to the appropriate NHREC-registered REC.

In a *no risk study* the completed template and proposal received from the SC are reviewed and the decision of the SC ratified by the FREC, a pre-allocated ethics number (received from the research support office) provided to the study, a letter of decision provided to the researcher, as well as the research support office informed of the study with its allocated number. Note: The *letter of decision* has to indicate that the study has been reviewed, cleared and has no risk.

In a *low risk study* the ethics application is taken into full review by the FREC, a pre-allocated ethics number (received from the research support office) provided to the study, a letter of decision provided to the researcher, as well as the research support office informed of the study with its allocated number. Note: *The letter of approval* has to indicate that it has been reviewed, approved, the risk level and the period of approval, other requirements.

#### 5. NATIONAL HEALTH RESEARCH COUNCIL REGISTERED RESEARCH ETHICS COMMITTEE (NHREC-registered REC)

Specific circumstances that require referral to appropriately mandated RECs are indicated below:

- Should the study be ‘health or health-related’, statutory regulations require that review is by a NHREC-registered Health Research Ethics Committee, *for all low to high risk studies*.
- Should the study involve *animals*, statutory regulations require that review is by a NHREC-registered Animal Research Ethics Committee, *for all low to high risk studies*.
- Should the study be a *medium or high risk study* or involve *vulnerable participants*, the ethics application should be referred to an appropriate NHREC-registered REC, based on the focus of the study.
- Should the study topic otherwise fall outside the expertise of a particular FREC, this should also be referred to another FREC or NHREC-Registered REC with the appropriate expertise.

See table below for the detail explanation.

<p align="center"><b>NWU-HREC</b> (North-West University Health Research Ethics Committee)* REC-130913-037</p> <p><i>Note: Functions under the Ethics Office of the Faculty of Health Sciences</i></p>	<p align="center"><b>NWU-EMELTEN-REC</b> (North-West University Education, Management and Economics, Law, Theology, Engineering and Natural Sciences Research Ethics Committee)# REC-011216-053</p>	<p align="center"><b>NWU-HSSREC</b> (North-West University Human Social Sciences Research Ethics Committee)# REC-080615-047</p>	<p align="center"><b>NWU-AnimCareREC</b> (North-West University Animal Care, Health and Safety Research Ethics Committee)* AREC-130913-01</p> <p><i>Note: Functions under the Ethics Office of the Faculty of Health Sciences</i></p>	<p align="center"><b>NWU-AnimProdREC</b> (North-West University Animal Production Research Ethics Committee)# AREC-110913-014</p>
<p>Key factors for making decision:</p> <ol style="list-style-type: none"> <li>1) All health or health-related research</li> <li>2) Matching the focus of the study with the expertise of the REC</li> </ol> <p><b>Definition of health:</b> A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.</p>	<p>Key factors for making decision:</p> <ol style="list-style-type: none"> <li>1) Vulnerable participants</li> <li>2) Medium to high risk studies</li> <li>3) Not health or health-related studies</li> </ol> <p>Not in the Humanities or Social sciences.</p>	<p>Key factors for making decision:</p> <ol style="list-style-type: none"> <li>1) Studies within the broad field of humanistic disciplines that research human functioning in social, political, institutional, cultural and historical environments and developmental contexts.</li> <li>2) Other studies in the Faculty of Humanities that involve medium to high risk studies or involve vulnerable participants.</li> </ol> <p>Not health or health-related studies</p>	<p>Key factors for making decision:</p> <ol style="list-style-type: none"> <li>1) The purpose of the study</li> <li>2) Matching the focus of the study with the expertise of the REC</li> </ol> <p>Determining if a study is focused on health (either animal or human), environmental or animal production sciences</p>	

<p><b>Definition of health research:</b></p> <ul style="list-style-type: none"> <li>• Research that contributes to biological, clinical, psychological or social welfare matters.</li> <li>• Causes and effects of and responses to disease.</li> <li>• Effects of the environment.</li> <li>• Health care systems</li> <li>• New pharmaceuticals, medicine, interventions, devices.</li> </ul> <p>New technologies to improve health or health care.</p> <p><b>Definition of health-related:</b></p> <p>Any research conducted by disciplines other than health disciplines about topics, systems or participants (patients or personnel) within the field of health or investigating or striving to improve the bio-psycho-social wellbeing of human participants.</p>				
<p>REC members:</p> <ol style="list-style-type: none"> <li>1) Health professionals and scientists</li> <li>2) Representation from educational psychology</li> <li>3) Representation from pastoral care</li> <li>4) Representation from metabolomics</li> <li>5) A member of NWU-EMELTEN-REC</li> <li>6) A member of NWU-HSSREC</li> <li>7) Across campus representation</li> <li>8) Head and/or advisory member from the Faculty of Health Sciences Ethics Office</li> </ol>	<p>REC members:</p> <ol style="list-style-type: none"> <li>1) Representation from all the mentioned faculties</li> <li>2) A member from NWU-HREC</li> <li>3) Across campus representation</li> </ol>	<p>REC members:</p> <ol style="list-style-type: none"> <li>1) Scientists from the Humanities and Social Sciences</li> <li>2) A member from NWU-HREC</li> <li>3) Across campus representation</li> </ol>	<p>REC members:</p> <ol style="list-style-type: none"> <li>1) Health and Environmental Scientists</li> <li>2) Representation from NWU-AnimProdREC</li> <li>3) Across campus representation</li> <li>4) Head and/or advisory member from the Faculty of Health Sciences Ethics Office</li> </ol>	<p>REC members:</p> <ol style="list-style-type: none"> <li>1) Scientist from Animal Production Sciences</li> <li>2) Representation from NWU-AnimCareREC (both health and Environmental Sciences)</li> <li>3) Across campus representation</li> </ol>

<p>Faculties:</p> <ul style="list-style-type: none"> <li>• Faculty of Health Sciences</li> <li>• Any other Faculty doing health or health related research</li> </ul> <p>Groups:</p> <ul style="list-style-type: none"> <li>• Health professionals</li> <li>• Health scientists</li> <li>• Scientist from fields associated to health e.g. biochemistry</li> <li>• Educational psychology</li> <li>• Theology focused on counselling of vulnerable groups</li> </ul>	<p>Faculties:</p> <ul style="list-style-type: none"> <li>• Education</li> <li>• Management and Economics Sciences</li> <li>• Law</li> <li>• Theology</li> <li>• Engineering</li> <li>• Natural Sciences</li> </ul>	<p>Faculties:</p> <ul style="list-style-type: none"> <li>• Humanities (including Social Sciences)</li> </ul>	<p>Faculties:</p> <ul style="list-style-type: none"> <li>• Health Sciences</li> <li>• Natural Sciences (Environmental Sciences)</li> <li>• Faculty of Engineering</li> <li>• Any Faculty using animals for health or health-related purposes</li> </ul>	<p>Faculties:</p> <ul style="list-style-type: none"> <li>• Natural Sciences (Agriculture)</li> <li>• Faculty of Engineering</li> <li>• Health Sciences if for animal production purposes</li> </ul>
<p>Criteria:</p> <ul style="list-style-type: none"> <li>• Research of researchers registered as health professionals</li> <li>• Research of health scientists</li> <li>• Health or health-related research (Note: <b>All risk levels</b> must be sent to the NWU-HREC)</li> <li>• Research about health personnel</li> <li>• Research about health systems</li> <li>• Research to create devices to be used to improve the health of an individual</li> <li>• Using human samples</li> <li>• Giving humans substances</li> </ul>	<p>Criteria:</p> <ul style="list-style-type: none"> <li>• Vulnerable participants</li> <li>• Medium to high risk studies</li> <li>• Participants not from a health or health-related context</li> <li>• All themes except those specifically related to Health, Humanities and Social Sciences</li> </ul>	<p>Criteria:</p> <ul style="list-style-type: none"> <li>• Vulnerable participants</li> <li>• Medium to high risk studied</li> <li>• Participants not from a health or health-related context</li> <li>• Themes specifically related to Humanities and Social Sciences</li> </ul>	<p>Criteria:</p> <ul style="list-style-type: none"> <li>• Research of researchers registered as health professionals, involving animals</li> <li>• Research of health scientists, involving animals</li> <li>• Animals involved in research for the purpose of human health</li> <li>• Animals involved in research for the purpose of animal health</li> <li>• Animals involved in research for the purpose of environmental health</li> </ul>	<p>Criteria:</p> <ul style="list-style-type: none"> <li>• Animals involved in research for the purpose of improving animal breeding</li> <li>• Animals involved in research for the purpose of improving animal nutrition, genetics and reproduction</li> </ul>

\* Required by law to be NHREC-registered RECs

# Registered at the NHREC to ensure a standard of nationally benchmarked ethics review as well as the additional protection of vulnerable participants, researchers and the NWU as well as focused review of greater than low risk studies

## APPENDIX A: ETHICS CLEARANCE FLOW PROCESS

### Scientific review by a Faculty Scientific/Proposal Committee (SC)

#### Actions by the SC:

Review *all research* applications and *refer all studies* to the appropriate Research Ethics Committee (REC) for ethics clearance.

- *No risk studies:*  
Issue a letter of scientific approval to the researcher  
Complete a template, attach the proposal and send to the FREC for ethical clearance.
- *Low risk studies:*  
Issue a letter of scientific approval to the researcher that they have to attach to the ethics application to the REC  
Refer the researcher *to the FREC* (Note: Except if health or health related research to the NWU-HREC; if animal studies to the NWU-AnimCare-REC or NWU-AnimProd-REC)
- *Medium to high risk studies or a study involving vulnerable participants:*  
Issue a letter of scientific approval to the researcher that they have to attach to the ethics application to the REC  
Refer the researcher to the *appropriate NHREC-registered REC* (based on the scope of the RECs)
- All *health or health-related studies* irrespective of the risk level has to be referred to the *NWU-HREC*  
Issue a letter of scientific approval to the researcher that they have to attach to the ethics application to the REC  
Refer the researcher to the NWU-HREC
- All *animal studies* irrespective of the risk level has to be referred to *either the NWU-AnimCare-REC or NWU-AnimProd-REC*  
Issue a letter of scientific approval to the researcher that they have to attach to the ethics application to the REC  
Refer the researcher to the NWU-AnimCare-REC or NWU-AnimProd-REC
- A study with a *potential negative impact on the environment* should be referred to the *appropriate NHREC-registered REC*  
Issue a letter of scientific approval to the researcher that they have to attach to the ethics application to the REC
- A study with *potential reputational damage to the NWU* should be referred to the *appropriate NHREC-registered REC*  
Issue a letter of scientific approval to the researcher that they have to attach to the ethics application to the REC





**Ethical clearance by the appropriate REC**

<b>No risk</b>	<b>Low risk</b>	<b>Human studies or impact on the environment</b>	<b>Animal studies</b>	
		<b>Medium or high risk studies or a study involving vulnerable participants</b>		
<b>Ratification by the REC of the recommendation by the SC</b>	<b>Full review by the REC</b>	<b>Full review by the appropriate NHREC-registered REC</b>	<b>Full review by the appropriate NHREC-registered REC</b>	
<p>FREC</p> <p>NWU-HREC for health or health-related studies</p> <p>NWU-AnimCare-REC or NWU-AnimProd-REC for animal studies</p> <p>Review template and proposal sent by the SC and ratifies the recommendation of the SC</p>	<p>FREC</p> <p>NWU-HREC for health or health-related studies</p> <p>NWU-AnimCare-REC or NWU-AnimProd-REC for animal studies</p> <p>Conducts either an expedited or full face-to-face review of the ethics application received from the researcher</p>	<p>All health and health-related studies (NWU-HREC)</p> <p>All studies in Humanities (NWU-HSSREC)</p> <p>All other studies that is not health or health-related or from Humanities (NWU-EMELTEN-REC)</p>	<p>Animal studies about:</p> <p>*Human health</p> <p>*Animal health</p> <p>*Environmental health (NWU-AnimCareREC)</p>	<p>Animal studies about:</p> <p>*Improving animal breeding</p> <p>*Improving animal nutrition, genetics and reproduction (NWU-AnimProdREC)</p>

### Actions by REC

<p>Obtain a pre-allocated ethics number from the research support office</p> <p>Provide an ethics number to the study</p> <p>Letter to the researcher of the REC's decision (review, ratification of the SC decision, no risk)</p> <p style="color: red;">After consideration by the REC, send the allocated ethics number to the research support office to be captured on VSS</p>	<p>Obtain a pre-allocated ethics number from the research support office</p> <p>Provide an ethics number to the study</p> <p>Letter to the researcher of the REC's decision (review, approval, risk level, period of approval, other requirements)</p> <p style="color: red;">After consideration by the REC, send the allocated ethics number to the research support office to be captured on VSS</p>	<p>Obtain a pre-allocated ethics number from the research support office</p> <p>Provide an ethics number to the study</p> <p>Letter to the researcher of the REC's decision (review, approval, risk level, period of approval, other requirements)</p> <p style="color: red;">After consideration by the REC, send the allocated ethics number to the research support office to be captured on VSS</p>	<p>Obtain a pre-allocated ethics number from the research support office</p> <p>Provide an ethics number to the study</p> <p>Letter to the researcher of the REC's decision (review, approval, risk level, period of approval, other requirements)</p> <p style="color: red;">After consideration by the REC, send the allocated ethics number to the research support office to be captured on VSS</p>	<p>Obtain a pre-allocated ethics number from the research support office</p> <p>Provide an ethics number to the study</p> <p>Letter to the researcher of the REC's decision (review, approval, risk level, period of approval, other requirements)</p> <p style="color: red;">After consideration by the REC, send the allocated ethics number to the research support office to be captured on VSS</p>
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### Scope of NWU SCs and RECs August 2019

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